IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

INMAR RX SOLUTIONS, INC.,	§	
	§	
***Plaintiff*,**	§	
	§	
v.	§	
	§	
MERRICK B. GARLAND, in his official capacity as U.S. Attorney General, UNITED STATES DEPARTMENT OF JUSTICE, ANNE M. MILGRAM, in her official capacity as Administrator of the Drug Enforcement Administration, and UNITED STATES DRUG ENFORCEMENT ADMINISTRATION,	§	**Civil No. _____**
	§	
***Defendants*.**	§	

COMPLAINT AND REQUEST FOR
DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff Inmar Rx Solutions, Inc. (Inmar), by this Complaint against the United States Department of Justice, Attorney General Merrick B. Garland, the Drug Enforcement Administration (DEA), and its Administrator Anne M. Milgram, alleges as follows:

INTRODUCTION

1. This action for injunctive and declaratory relief arises from Defendants' attempt to subject Inmar to unconstitutional proceedings before a DEA administrative law judge (ALJ).

2. On September 27, 2023, Defendant DEA issued an Order to Show Cause (OSC) against Inmar seeking to revoke Inmar's DEA Certificate of Registration. The OSC poses a significant threat to the company. Under the Controlled Substances Act (CSA) and its implementing regulations, Inmar is required to maintain this Certificate of Registration to handle and engage in reverse distribution of controlled substances. As a result, when Inmar received the

OSC from DEA, it was faced with a stark choice: either default and lose its registration automatically or defend itself against the OSC's allegations in the DEA's ALJ-overseen adjudication. Inmar is thus compelled to participate in the DEA's adjudicatory proceedings.

3. That does not mean the ALJ proceedings should go forward. Under binding precedent, those proceedings violate Article II of the Constitution of the United States. As the Fifth Circuit held in *Jarkesy v. SEC*, 34 F.4th 446 (5th Cir. 2022), the two-layer, for-cause removal restrictions applicable to ALJs impermissibly impair the President's constitutional charge to take care that the laws are faithfully executed. The same restrictions on for-cause removal at issue in *Jarkesy* are at issue here. Specifically, Sections 7521(a) and 1202(d) of Title 5 of the United States Code prevent the President and Attorney General from removing DEA ALJs unconditionally. Rather, ALJs may be removed only for "good cause" as "determined" by the Merit Systems Protection Board ("MSPB"), whose members themselves can be removed by the President only on certain limited "good cause" grounds. This degree of insulation is unconstitutional. Indeed, because DEA ALJs do not satisfy either narrow recognized exception to the President's unrestricted removal power, *any* degree of insulation is unconstitutional.

4. The DEA's revocation proceeding has stakes that extend beyond Inmar. As the nation's largest reverse pharmaceutical distributor—in essence, a processor of pharmaceutical returns—Inmar serves nearly 25,300 customers, including retail pharmacy chains,[1] clinics, independent pharmacies, and hospitals; all 3 major pharmaceutical wholesalers; 194 pharmaceutical manufacturers; and in 2023, substantively serviced returns for the U.S. Department

[1] Although Inmar treats its retail pharmacy chains as a single "customer," Inmar in fact provides reverse pharmaceutical distribution services to each of the individual pharmacies in those chains, totaling 38,139 individual pharmacies as of June 30, 2023.

of Health and Human Services (HHS). Inmar is responsible for the vast majority[2] of the pharmaceutical returns business nationwide. Inmar's customers depend on its continued operations and the nationwide infrastructure it has built to support the country's pharmaceutical industry by ensuring the safe and compliant destruction of otherwise dangerous pharmaceuticals; the timely and effective return of pharmaceuticals for credit (which its customers then use to purchase new pharmaceuticals, as well as other compliance solutions offered by Inmar); and the secure storage of controlled substances to prevent potential diversion.

5. Nor has the DEA articulated any grounds that would justify a revocation of Inmar's registration. The DEA's allegations in the OSC are based on assertions that Inmar did not fully comply with implementing regulations of the CSA and, separately, a Memorandum of Agreement (MOA) that Inmar signed in 2022. Those allegations are variously overstated, unfounded, or reliant on overbroad interpretations of regulatory language.

6. Inmar should not, however, be forced to defend itself under the DEA's constitutionally illegitimate regime. As the Supreme Court has recognized, being subjected to an unconstitutional proceeding is an independent, immediate, "here-and-now" injury—one that cannot be remedied through normal channels of appeal. *See Axon Enter., Inc. v. Fed. Trade Comm'n*, 598 U.S. 175, 191-92 (2023).

7. The DEA, for its part, has no immediate need to proceed with a constitutionally defective process. The DEA did not seek an Immediate Suspension Order (ISO) to shut down Inmar, which it would have done in the event it perceived an "imminent danger to the public health or safety." 21 U.S.C. § 824(d). Instead, following an inspection in April 2023 that ostensibly prompted the OSC, DEA officials waited months to initiate proceedings.

[2] Inmar estimates that it supports over 75% of the pharmaceutical returns business.

8. Even now, the DEA has not identified Inmar as a cause of theft, loss, or drug diversion, nor has it suggested Inmar poses any imminent threat to public health or safety. To the contrary, the DEA clarified that it does not have concerns about diversion or the physical integrity of Inmar's operations, and it has permitted Inmar to continue to operate during the pendency of the ALJ proceedings.[3] In addition, Inmar has continued to implement new measures to bolster its existing compliance programs since the DEA's last inspection, rendering moot many of the concerns that the DEA has expressed to Inmar.

9. Inmar moves accordingly for all necessary relief to enjoin the DEA's administrative action against the company until the constitutional defects in its enforcement regime can be remedied.

PARTIES

10. Plaintiff Inmar Rx Solutions, Inc. is a Texas corporation headquartered at One West Fourth Street, Suite 500, Winston-Salem, North Carolina 27101, with its primary operational facility at 3845 Grand Lakes Way #125, Grand Prairie, Texas 75050.

11. Defendant Merrick B. Garland is named in his official capacity as the Attorney General of the United States. By statute, the Attorney General has the authority to enforce the CSA. The Attorney General has delegated relevant enforcement authority to the DEA Administrator. *See* 28 C.F.R. § 0.100. The address of the Office of the Attorney General is 950 Pennsylvania Avenue NW, Washington, DC 20530.

12. Defendant United States Department of Justice is an executive department of the United States. *See* 5 U.S.C. § 101; 28 U.S.C. § 501. The head of the Department of Justice is the

[3] Indeed, DEA issued Inmar's annual controlled substances license renewal on October 12, 2023, after it had issued the OSC.

Attorney General. *See* 28 U.S.C. § 503. The address for the DOJ is 950 Pennsylvania Avenue NW, Washington, DC 20530.

13. Defendant Anne M. Milgram is named in her official capacity as the Administrator of the DEA. The Attorney General's authority to enforce the CSA has been delegated to her. *See* 28 C.F.R. § 0.100. The Address of the Office of DEA Administrator is 8701 Morrissette Drive, Springfield, Virginia 22152.

14. Defendant Drug Enforcement Administration is a component of the United States Department of Justice. The DEA was created by Executive Order 11,727. 38 Fed. Reg. 18357 (July 10, 1973). The address for the DEA is 8701 Morrissette Drive, Springfield, Virginia 22152. It has jurisdictional authority across the United States.

JURISDICTION AND VENUE

15. This action arises under Article II of the United States Constitution and the Declaratory Judgment Act. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because the action arises under the laws of the United States.

16. Venue is proper in this district under 28 U.S.C. § 1391(e)(1) because plaintiff resides in this district and a substantial part of the events or omissions giving rise to this action occurred in this district.

FACTUAL ALLEGATIONS

A. Inmar Rx Solutions, Inc.

17. Plaintiff Inmar, formerly known as Med-Turn, Inc., is a wholly owned subsidiary of Inmar, Inc. The company has been in existence for over 30 years. Since obtaining its initial registration with the DEA in drug Schedules I through V on January 28, 1994, Inmar has grown to become the largest reverse pharmaceutical distributor in the country. Its customer base includes

over 25,000 customers, including the largest pharmacy chains (totaling over 38,000 individual pharmacies), the vast majority of hospitals and health systems in the United States, and the three largest pharmaceutical distributors. All told, Inmar estimates that it handles more than 75% of the pharmaceutical returns business nationwide, and nearly the entirety of the industry's wholesale returns.

18. A reverse pharmaceutical distributor is a company that receives pharmaceuticals from wholesalers, retail sellers, or healthcare facilities for the purpose of returning unwanted, unusable, or outdated pharmaceuticals to the manufacturer or another entity for credit value. In most cases, the reverse distributor is in charge of the proper disposal of the returned pharmaceuticals. Reverse distributors that handle controlled substances, like Inmar, are also subject to regulatory requirements pursuant to the CSA and regulations promulgated by DEA.

19. With decades of experience, Inmar has become particularly adept in the services it provides to its thousands of customers in the reverse distribution space.

20. When its pharmacy customers and manufacturers need to safely dispose of expired pharmaceutical products, including controlled substances, Inmar undertakes responsibility for doing so safely in compliance with standards set by the DEA and Environmental Protection Agency (EPA). In addition to assisting in the receipt, inventory assessment, secure storage, and disposal of pharmaceuticals, Inmar helps its clients—including independent retail pharmacies, large chain pharmacies, and hospital pharmacies—to identify pharmaceuticals eligible for manufacturer return credits and, in some instances, to hold those pharmaceuticals until a determination can be made as to whether the manufacturer will accept a return of the product or requests to have the product destroyed.

21. Inmar facilitates manufacturer return credits by coordinating the return of the products from retail pharmacies to Inmar's Grand Prairie facility where the products are securely stored until the appropriate return authorization and regulatory paperwork is received and a determination is made as to whether the respective retailer or manufacturer seeks a return at all. Once authorization for credit and disposition directives are received from the supplier, Inmar processes the product accordingly.by either by sending it for destruction or shipping the product back to the manufacturer or their agent while ensuring that the pharmacies receive their product credits. These credits help those hospitals and pharmacies pay for new drug orders.

22. Inmar also provides pharmaceutical recall services to manufacturers for both controlled and non-controlled substances. Inmar serves either as the manufacturers' sole contracted reverse pharmaceutical wholesaler (in which case Inmar accepts recalled product from pharmacies and stores it until the manufacturer makes a final determination on what to do with the product), or as a recall point (in which case Inmar accepts recalled product from its preexisting pharmacy customers and transmits it to the manufacturer's point of final determination).

23. Inmar has historically provided reverse pharmaceutical wholesale services to a number of governmental entities, including the Strategic National Stockpile (SNS) under the oversight of the Office of the Assistant Secretary for Preparedness and Response (ASPR) in HHS.

24. On an average day in 2023, Inmar processes incoming shipments of approximately 355,000 pieces (a "piece" is typically in the form of a pill bottle) of prescription pharmaceuticals and approximately 52,000 pieces of controlled substances, which encompasses 228 different drug types. This translates to approximately 2.3 million controlled substance dosage units (e.g., pills) processed per day. In the past, the DEA has commended Inmar for having one of the "superior" inbound processes as compared to similar registrants.

25. To be received at an Inmar facility, these millions of daily dosage units must be prepared, packaged, and organized for shipping by each customer; shipped in coordination with UPS, FedEx, and other common carriers, which are selected by the customer; and then received at Inmar's facilities to be inventoried, handled, stored, and evaluated for further action at the customer's direction. Notably, common carriers are not subject to DEA regulation.

26. Given the volume of shipments and the involvement of common carriers, it is practically impossible for Inmar to assess these shipments before taking possession of them. Inmar cannot intercept shipments in an unsecured parking lot, open them, and conduct an inventory—all before the common carrier leaves the premises. Instead, Inmar receives all shipments at its secure facility, sorts the material, and conducts a careful count of controlled substances to maintain an accurate inventory, all as previously approved by the DEA in 2019 as the Grand Prairie facility was being made ready for the business operation transfer from the prior Fort Worth location.

27. The DEA has recognized that reverse distributors face unique challenges in processing returns and expired drugs. As a reverse distributor, Inmar must identify and provide special procedures for the handling and security of controlled substances when they arrive at the facility. When shipping product to Inmar, the vast majority of Inmar's customers segregate their controlled substances from their non-controlled substances. However, some of Inmar's customers, including a large chain customer (with thousands of individually licensed pharmacies across all fifty states), regularly combine non-controlled substances with Schedule III-V controlled substances when shipping to Inmar.[4]

28. The required processing, control, and storage of the customers' products, at scale, is a task that Inmar has demonstrated unique aptitude and infrastructural capabilities to handle.

[4] Inmar also has a special caged area within its facility for processing these returns with the knowledge and consent of the DEA.

Inmar's geographical coverage and resources dedicated to its reverse logistics services are unmatched, and it has become the unquestioned leader in the space. Inmar's scale of operations makes it uniquely positioned to provide services and product solutions that no other reverse distributor can.

29. The most critical piece of Inmar's business and national infrastructure is its modernized DEA-registered processing facility in Grand Prairie. Through this hub, Inmar combines all aspects of its supply chain operations into one geographically central location.

30. Most reverse-distributed pharmaceuticals in the country pass through the Grand Prairie facility. This includes more than just Inmar's shipments. Many other pharmaceutical reverse distributors in the country also pass shipments through this location. The nation's largest pharmaceutical forward distributors—including Cardinal Health, AmerisourceBergen, and McKesson—rely on the facility as one of their designated return depots. This is in addition to 14 of the top 20 drug manufacturers that use Inmar to process their returns at the facility as well.

31. Controlled substances are received, handled, and stored at the Grand Prairie facility within a 5,000-square-foot DEA-approved vault, which is nested within a 350,000-square-foot secure facility. The facility is continuously monitored with over 220 cameras and boasts an on-site security team of 25.

32. Inmar uses a state-of-the-art "Itag" system to manage its controlled substances inventory. An Itag is a unique identifier in the form of a barcoded sticker that is generated and applied to each container of controlled substances once the container has been received and after *the exact quantity* of dosage units (e.g., pills) has been counted and recorded.[5] Itag tracking therefore allows Inmar to determine at any given moment the precise quantity of controlled

[5] Indeed, Inmar does so for *all* substances in its inventory, although DEA regulations only require *estimates* for Schedule III-V substances.

substances on hand, down to the quantity of individual pills. Such a system is critical to meet the challenges of reverse distributors, like Inmar, that often receive product in varying states of packaging.

33. Inmar maintains all necessary licenses, permits and certifications required by the Resource Conservation and Recovery Act, Clean Air Act, Clean Water Act, and Occupational Safety and Health Administration, and all licenses and permits required by DEA as well as local and state agencies for reverse distribution operations and handling of controlled and hazardous substances. It has a dedicated team to ensure uninterrupted compliance with federal regulations, including, perhaps most importantly, the CSA.

B. Inmar's DEA Registration is Conditioned Upon Compliance with the CSA, Subject to the DEA's Review and Enforcement

34. Inmar's registered activities as a reverse distributor are governed in part by the CSA and its implementing regulations. 21 U.S.C. § 801 *et seq.*; *see also* 21 C.F.R. § 1300 *et seq.* These authorities prescribe standards governing the receipt of controlled substances, inventory requirements, recordkeeping, and disposal protocols, and include other measures registrants must follow.

35. The DEA is tasked with enforcing the CSA, within the confines of that statute and implementing regulations "to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial purposes." 76 Fed. Reg. 39,318-01 (July 6, 2011). As with all agencies, the DEA's rulemaking and enforcement authority extends no further than statute and regulations allow.

36. Once an entity has been approved and registered with the DEA to manufacture, distribute, or dispense controlled substances, its registration may be suspended or revoked by the

government only in limited circumstances. Before taking action to revoke, restrict, or suspend a DEA registration under 21 U.S.C. § 824(a), the DEA and DOJ generally must first provide the registrant with notice and an opportunity to be heard—that is, an order to show cause and an opportunity for a hearing. *See* 21 U.S.C. § 824(c). In extraordinary circumstances, however, the DEA may issue an ISO if the registrant's actions pose "an imminent danger to the public health or safety," 21 U.S.C. § 824(d), which effectively shuts down a registrant's regulated operations prior to agency adjudication.

C. Inmar Comes Under Supervision of the Dallas DEA Office and Receives an Inspection Resulting in a Memorandum of Agreement

37. As a DEA registrant, Inmar has worked closely and collaboratively with the DEA for decades to ensure the safety and compliance of its operations. Inmar's Texas facilities historically were monitored by the DEA's Fort Worth office, largely without incident over Inmar's many years of operations. The DEA continued to renew Inmar's registration each year without limitation.

38. In 2019, Inmar began the process of building out its state-of-the-art warehouse facility in Grand Prairie, Texas, which placed it under the jurisdiction of the DEA's Dallas Field Division.

39. Inmar's original construction and security plans (which included the operational layout, physical controls, electronic controls, and operational controls) were approved by the DEA in July 2019, and the facility opened in January 2020. Thereafter, the DEA approved the new registration for Inmar's Grand Prairie facility, finding that such registration was in the public interest.

40. As a DEA registrant, Inmar is subject to periodic unannounced inspections and audits at reasonable times. *See* 21 U.S.C. § 880. In April 2021, the DEA conducted one such

inspection related, in part, to examining Inmar's inventory records. This inspection noted a recordkeeping gap related to one pallet of products received from one of Inmar's customers, but there was no determination of any product diversion. The pallet had been designated for destruction and was, in fact, destroyed.

41. In its communications with Inmar, the DEA expressed no genuine concern at the time that the unrecorded product had been stolen or diverted. Nonetheless, as soon as the inspection was completed, Inmar began implementing measures to mitigate the risk of similar isolated instances in the future and to facilitate DEA oversight over Inmar's recordkeeping procedures.

42. Over the ensuing months, Inmar regularly apprised the DEA of the implementation of certain measures it had, on its own initiative, adopted to address the DEA's professed concerns. The DEA agreed that these additional procedures—not required by the CSA or regulations promulgated by the DEA—were appropriate. The proposals were not believed to be controversial at the time, but rather a means to enhance existing cooperation. The terms of Inmar's new procedures and protocols were set forth in the MOA executed between the DEA and Inmar in January 2022. The MOA expressly states that it may "not be modified, unless in writing, and both parties agreeing to such modifications."

43. Inmar launched a significant and comprehensive program to guarantee compliance with the new protocol agreed to with the DEA. Inmar has also implemented additional measures over and above the requirements of the MOA and DEA regulations.

D. The DEA Conducts Another Inspection, Voices New Concerns, and Waits Months to Serve an Order to Show Cause

44. In April 2023, DEA Diversion Investigators from the Dallas Field Division conducted an authorized on-site inspection at Inmar's Grand Prairie facility. The inspection

encompassed a tour of the facility, a review of Inmar's security measures, and an audit of selected controlled substances.

45. Following the inspection, the DEA purported to identify "breaches" of governing regulations and the MOA that had no basis in the law, the MOA, or elsewhere.

46. The novelty and unprecedented nature of the DEA's perspective notwithstanding, Inmar has, since the inspection, voluntarily implemented changes to its recordkeeping procedures to address every purported shortcoming the DEA identified.

47. Five months passed after the DEA conducted its inspection. Inmar continued to communicate with the DEA, apprising it of the additional steps it was undertaking and repeatedly requesting dialogue to discuss any ongoing concerns. Then, on September 27, 2023, the DEA issued an OSC against Inmar, initiating administrative proceedings to decide whether Inmar's continued DEA registration is in the public interest. The OSC contains no allegations of any diversion, theft, or loss of pharmaceutical products.

48. Nevertheless, four days after the OSC, on October 31, the DEA issued a press release titled "DEA Executes Operation Bottleneck to Prevent the Diversion of Controlled Substances and Keep Communities Safe." In addition to Inmar, it identifies five other companies with no material connection to Inmar. It asserts that Inmar "failed to comply with its obligation to maintain effective controls against the diversion of controlled substances," and its "violations include[d] the persistent failure to properly report theft or significant loss." The press release has caused substantial confusion among Inmar's customers, suggesting that Inmar had actual issues with diversion and theft.

49. DEA counsel has since reaffirmed that there were no physical security issues, thefts or losses, or diversion of any pharmaceutical products from Inmar's Grand Prairie facility. DEA

counsel confirmed this at a prehearing conference before DEA Chief ALJ John Mulrooney on November 14, 2023.

50. The OSC itself states four grounds for revocation, which Inmar will—when given the opportunity in a constitutionally sound proceeding—refute.

51. **First**, the DEA contends that Inmar did not comply with regulatory requirements that a reverse distributor "[p]romptly deliver [its] controlled substance[s]" as received "to the manufacturer or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf," or "[t]imely destroy the controlled substance[s]." OSC at 3 (citing 21 C.F.R. § 1317.15(c)(2), (3)). Although Inmar has operated as it currently does for years—and its activities are consistent with widespread industry practice—this is the first time that the DEA has *ever* mentioned any potential compliance issues on this score. After all, Subsection 1317.15(c)(1) of this same regulation authorizes a reverse distributor to "store [] controlled substances, in accordance with the security controls in [21 C.F.R. §§ 1301, 1307], at the reverse distributor's registered location . . . ***until timely destruction or prompt return*** of the controlled substance to the registered manufacturer or other registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf." Consistent with this provision, Inmar leverages its state-of-the-art secure storage facilities to safeguard product pending its customers' decisions to proceed with returns or destruction. It has done so for years, as the regulations permit.

52. **Second**, the OSC alleges that Inmar did not maintain accurate records of particular controlled substances on hand at its facility. The DEA specifically claims that there are gaps in Inmar's inventory recordkeeping based on the DEA's "conducting an inventory of certain controlled substances present at [Inmar's] registered location and comparing that inventory to the records maintained and provided by [Inmar]." OSC at 4. This assertion by the DEA appears to be

based on its analysis of an initial "drug name" report that the DEA requested during the onsite visit.[6] However, Inmar was unable to dig deeper into the accuracy of the DEA's inventory assessment as the DEA did not provide any detailed feedback on its inventory evaluation at the time of its April inspection or in the five months that followed—that is, until the filing of the OSC.

53. **Third**, the DEA asserts that Inmar's Form 106 submissions—which it is required to file to report "theft or losses"—incorrectly reported "a false number of thefts of losses experienced in the past 24 months." OSC at 5. This appears to be a reference to a shortcoming of the DEA's own electronic Form 106 submission form, which limits the number of digits that may be entered in the field for thefts or losses in the past 24 months. Inmar correctly input theft and loss information within the parameters provided by the DEA's system, and also reported pharmaceuticals that never reached Inmar's facilities from customers or third-party common carriers. Because 99% of the theft and loss reports filed by Inmar relate to conduct occurring before the pharmaceutical products reach Inmar's facility, they do not concern Inmar's losses—they occur in the custody of common carriers. But in all events, any issues the DEA alleges with respect to the total number of past DEA Form 106 reports input by Inmar into the DEA portal arises because the DEA portal does not permit those total numbers to be entered. And the DEA maintains its own records of Inmar's submissions, so it has these totals available. Importantly, there is no allegation that Inmar failed to report any theft or loss that it was required to report.

[6] The DEA's Fort Worth Field Office previously conducted accountability audits of Inmar's inventory based on National Drug Codes (NDCs) and determined that Inmar was in compliance with DEA recordkeeping and reporting requirements. Inmar's systems query its inventory database by NDCs by default because NDCs allow for greater precision; the same drug may be (and typically is) associated with multiple brand names, generic names, abbreviations, nicknames, and alternate spellings or misspellings. During the April investigation, the DEA sought reporting by "drug name" rather than NDC, and the DEA team was reminded that NDCs were entered into Inmar's on-hand system of record.

54. **Fourth**, the DEA contends that Inmar breached the January 7, 2022 MOA by not performing monthly "inventory accountability audits." But this purported "breach" is based, in large part, on whether the inventory audits that Inmar did perform were done in accordance with the DEA Dallas Field Office's internal expectations, beyond the MOA and any regulatory requirement.

E. The Stakes: A Revocation Order Would Be Catastrophic to Inmar, Risk Significant Diversion, and Disrupt the Industry

55. The stakes of how the OSC is resolved could not be higher for Inmar, its customers, and the pharmaceutical industry. The scope of Inmar's business and its critical role in the reverse distribution industry mean that a revocation of its DEA registration would have catastrophic consequences. It would almost certainly put an end to Inmar's existence as an ongoing business, and cause disruptions across the pharmaceutical industry and to the general public.

56. As of the date of this filing, Inmar holds reverse distribution and other ancillary operational contracts with over 25,000 companies in the pharmaceuticals industry. And many of these companies depend on the infrastructure that Inmar has built in the reverse distribution sector to support their businesses, secure controlled substances in secured facilities, and assist hospitals and pharmacies to obtain the manufacturer product credits.

57. The vast majority of Inmar's customer contracts require processing of both controlled *and* non-controlled substances, and many customers have no ability to track those returns and credits separately. If Inmar loses its registration, thousands of retail and independent pharmacies—including some of the largest retail chains in the country, hospital and health care systems, and other registered entities—will lose a principal destination for their pharmaceutical returns and equally importantly, valuable credit that is impacted by even the shortest pause to Inmar's operations. That, in turn, would lead to disruption within the pharmaceutical supply chain

and may oblige customers who cannot rely on Inmar's secondary facilities to discard pharmaceuticals that would otherwise be returned for credit. For some customers—including a major national pharmacy chain, Inmar's largest—finding a replacement for Inmar could take months, and any such replacement (if the customer could find one) would necessarily have infrastructure inferior to Inmar's.

F. The Immediate, Ongoing Injury: DEA's ALJ-Overseen Administrative Enforcement Structure Is Unconstitutional

58. By serving the OSC, the DEA initiated administrative enforcement proceedings styled *In the Matter of Inmar Rx Solutions, Inc.*, Docket No. 24-4. Chief ALJ John J. Mulrooney, II has been appointed to oversee the adjudication.

59. Like all DEA ALJs, Chief ALJ Mulrooney is empowered to oversee adjudications, up to and including an evidentiary hearing, and make recommendations to the Administrator about how to resolve them. This structure suffers from constitutional defects rendering the decision-making process *per se* illegitimate.

60. DEA ALJs are "officers" for purposes of Article II of the U.S. Constitution. They preside over administrative proceedings, occupy a continuing office established by law, and exercise significant authority. *See* 21 C.F.R. §§ 1316.52, 1316.42(f). They receive a career appointment and are exempt from probationary periods that apply to certain other government employees. 5 C.F.R. § 930.204(a).

61. It is the law of this Circuit that Article II "forbids" ALJs, as "officers," from operating with "two layers of for-cause protection." *Jarkesy*, 34 F.4th at 465.

62. Like the SEC ALJs at issue in *Jarkesy*, DEA ALJs are insulated by the same two layers of protection, because both are governed by the same statutory provisions that establish these protections. First, DEA ALJs are removable only for cause. 5 U.S.C. § 7521(a). Thus, an

ALJ can be removed only if "good cause" is "established and determined" by the Merit Systems Protection Board. *Id.* Second, members of the MSPB, in turn, can be dismissed by the President (or one lawfully acting on the President's behalf) "only for inefficiency, neglect of duty, or malfeasance in office." 5 U.S.C. § 1202(d). Thus, "if the President wanted [a DEA] ALJ to be removed, at least two layers of for-cause protection stand in the President's way." *Jarkesy*, 34 F.4th at 465. Trammeling presidential authority in this way is per se unconstitutional. *Id.*

63. Beyond the two-layer structure *Jarkesy* confirmed to be unlawful, DEA ALJs are unconstitutionally shielded from removal by any layer of protection. The "general rule" is that the President has "unrestricted removal power" over subordinate officers. *Seila Law LLC v. CFPB*, 140 S. Ct. 2183, 2198 (2020). There are only "two exceptions" to this general rule—neither of which apply. *Id.* at 2199. DEA ALJs obviously do not meet the exception for "multimember expert agencies that do not wield substantial executive power." *Id.* at 2199-200. Nor are they "inferior officers with limited duties and no policymaking or administrative authority." *Id.* at 2200. (emphasis added). The role of DEA ALJs is not limited in duration, scope, or substance. DEA ALJs make policy on a case-by-case basis; indeed, one of their roles is to assess whether continued registration is in "the public interest." 21 U.S.C. § 824. And they exercise substantial administrative authority in superintending adjudications. The general rule of Presidential removal therefore applies; a single layer of protection trammeling that right of removal violates the Constitution.

64. In addition, the Supreme Court has described being subjected to an "unconstitutionally structured decisionmaking process" as a "here-and-now" injury. *Axon*, 598 U.S. at 191-92. That injury cannot be rectified by submitting to the unconstitutional process and appealing afterwards. Inmar "will lose [its] rights not to undergo the complained-of agency

proceedings if [it] cannot assert those rights until the proceedings are over." *Id.* at 192. This, by definition, is irreparable injury. *See, e.g.*, *Scottsdale Cap. Advisors Corp. v. Fin. Indus. Regul. Auth., Inc.*, No. 23-cv-1506, 2023 WL 3864557, at *13 (D.D.C. June 7, 2023) (recognizing that "under the Supreme Court's explicit language" in *Axon*, "the nature of the constitutional claims asserted . . . suffice to show irreparable harm").

CAUSE OF ACTION

CLAIM ONE
Application for Injunctive Relief (U.S. Const. Art. II, §§ 1, 3)

65. Inmar repeats and realleges each and every allegation in paragraphs 1-64 above as if fully set forth here.

66. Inmar seeks a preliminary and permanent injunction to enjoin Defendants from continuing to subject it to unconstitutional administrative proceedings.[7]

67. Inmar satisfies all traditional factors for injunctive relief. It has a substantial likelihood of success on the merits of its claim because, under the binding precedent of *Jarkesy v. SEC*, the DEA ALJ adjudicatory structure is unconstitutional. Accordingly, Inmar faces continuing irreparable harm from being subjected to an unconstitutionally structured proceeding. The harm to Inmar, absent injunctive relief, far outweighs any harm to DEA if such relief is granted. And the grant of an injunction will serve the public interest by protecting parties' constitutional rights.

[7] At a pre-hearing conference, Chief ALJ Mulrooney stated that, barring unforeseen circumstances he could not then anticipate, he would stay the administrative proceedings if Inmar filed an action in district court challenging their constitutionality. In addition, Inmar and the DEA have made substantial progress trying to resolve amicably the DEA's underlying enforcement action against Inmar. Because of that progress, Inmar has delayed filing this action as long as possible but does so now to reserve its rights. Nevertheless, for the reasons just explained, Inmar may not need a preliminary injunction, and it will advise this Court accordingly if the ALJ issues an order staying those proceedings. Thereafter, Inmar would provide this Court with a status update depending on when the ALJ contemplates lifting the stay or if the underlying action is resolved by way of a settlement. Because the Supreme Court has agreed to review the Fifth Circuit's decision in *Jarkesy*, any stay should likely continue until the Supreme Court resolves that case.

CLAIM TWO
Declaratory Judgment (28 U.S.C. § 2201)

68. Inmar repeats and realleges each and every allegation in paragraphs 1-64 above as if fully set forth here.

69. Inmar requests a declaratory judgment that the statutes, regulatory provisions, and policies providing for removal of DEA ALJs are unconstitutional as applied by the DEA and DOJ.

PRAYER FOR RELIEF

For the foregoing reasons, Inmar Rx Solutions, Inc. respectfully requests that this Court enter judgment for Inmar on its claims and order the following relief:

1. Declarations that the statutes, regulatory provisions, and policies providing for removal of DEA ALJs are unconstitutional as applied by the DEA and DOJ;

2. Preliminary and permanent injunctive relief barring Defendants from administrative adjudicatory proceedings before any DEA ALJ, so long as the unconstitutional removal restrictions applicable to the ALJ have not been rectified; and

3 Such further and other relief as this Court may deem just and proper.

/s/ Brandon N. McCarthy

Gil M. Soffer (IL Bar No. 6201959)
(*pro hac vice application forthcoming*)
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, Illinois 60661
Telephone: (312) 902-5200
Facsimile: (312) 902-1061
gil.soffer@katten.com

Robert T. Smith (D.C. Bar No. 996033)
Timothy H. Gray (D.C. Bar No. 1720878)
(*pro hac vice applications forthcoming)*
KATTEN MUCHIN ROSENMAN LLP
1919 Pennsylvania Avenue NW – Suite 800
Washington, DC 20006

Telephone: (202) 625-3500
Facsimile: (202) 298-7570
robert.smith1@katten.com
timothy.gray@katten.com

Brandon N. McCarthy
State Bar No. 24027486
Ryan J. Meyer
State Bar No. 24088053
Ted A. Huffman
State Bar No. 24089015
KATTEN MUCHIN ROSENMAN LLP
2121 N. Pearl Street, Suite 1100
Dallas, Texas 75201
Telephone: (214) 765-3600
Facsimile: (214) 765-3602
brandon.mccarthy@katten.com
ryan.meyer@katten.com
ted.huffman@katten.com

COUNSEL FOR PLAINTIFF
INMAR RX SOLUTIONS, INC.